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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,962	02/02/2004	Darin G. Schaeffer	10703/042	9118

7590 01/10/2007
BRINKS HOFER GILSON & LIONE
ONE INDIANA SQUARE, SUITE 1600
INDIANAPOLIS, IN 46204

EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/769,962

Applicant(s)

SCHAEFFER ET AL.

Examiner

Shumaya B. Ali

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 12-31 is/are allowed.
6) ☒ Claim(s) 1,3-9 is/are rejected.
7) ☒ Claim(s) 10 and 11 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claim 2 has been cancelled, currently claims 1, and 3-31 are pending in the instant application.

Response to Arguments

Applicant's arguments see remarks, filed on 10/2/2006, with respect to claims 12-21 have been fully considered and are persuasive. Therefore, the previous rejection to claims 12-21 has been withdrawn.

Applicant's arguments with respect to claims 1-9 have been fully considered but they are not persuasive. Examiner acknowledges that limitation of claim 2 has been incorporated into currently amended claim, however such amendment to claim 1 does not render claim 1 patentable because limitation of claim 2 is considered rejected under 35 U.S.C. 102(b) as being anticipated by Fauza US Patent 6,612,305 B2. Fauza discloses "selective attachment (" A movable flange (3) allows for extra fixation of the device around a patient's neck", see abstract, see also col.4 lines 9-10) to said proximal end portion and detachment therefrom (Fauza's flange allows anchorability of the tube at a given position), said flange extending radially from said proximal end portion when attached thereto" as cited in claim 1. Thus, currently amended claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Fauza US Patent 6,612,305 B2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fauza US Patent 6,612,305 B2

As to claim 1, Fauza discloses a tracheotomy tube (see fig.2 reference object 2) comprising: a hollow tubular body (fig.2, 2) having a proximal end portion (proximal end is away from the body/toward flange 3), a distal end portion (opposite end of the proximal) and a curved portion intermediate said proximal and distal end portions (fig.2 depicts a curved portion between the distal and proximal end of the tube); and a flange (fig.2 reference object 3) situated at said proximal end portion, said flange being capable of “selective attachment (“ A movable flange (3) allows for extra fixation of the device around a patient’s neck”, see abstract, see also col.4 lines 9-10) to said proximal end portion and detachment therefrom (Fauza’s flange allows anchorability of the tube at a given position), said flange extending radially from said proximal end portion when attached thereto”

As to claim 8, Fauza discloses the tracheotomy tube of claim 1, further comprising a removable inner cannula (fig.2, 5) insertable in said hollow tubular body.

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As to claim 9, Fauza discloses the tracheotomy tube of claim 1, wherein said hollow tubular body includes an inflatable cuff (fig.2, 1) surrounding a part of said distal end portion, said tracheotomy tube further comprising an inflation line (see attached fig.2) connecting said cuff to a source (air, fig.2, 4) of an inflation fluid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fauza US Patent 6,612,305 B2

As to claim 3, Fauza does not disclose the tracheotomy tube of claim 2, wherein said flange is attachable to said tube by a snap-fit. However, applicant has not established criticalities regarding the type of fit used in the invention. Therefore, Fauza's disclosure of a flange with a strap attachment is considered an equivalent structure capable of securing the flange to the tube (col.4 lines 5-10).

Claims 4,6,7,23-28, and are rejected under 35 U.S.C. 103(a) as being unpatentable over Fauza US Patent 5,058,580 in view of Roy US Patent 6,135,110

As to **claim 4**, Fauza discloses the tracheotomy tube of claim 3, and wherein said flange includes a cut-away portion (see labeled fig.2, attachment below), collar (see labeled fig.2), however does not disclose wherein said collar having a groove, and said groove being cooperatively sized and shaped to mate when said flange is attached to said tube. As to claim 4, Roy teaches a tracheotomy tube with a snap ring that is rotatably mounted about a proximal end of the tube (col.2 lines 20-21) that are meant to mate with tabs for guiding the movement of tabs (col.4 lines 38-39). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the tube of Fauza in view of Roy in order to provide a collar at the proximal end of the tube which will be capable of guiding and preventing movements inside the tube.

As to **claim 6**, Fauza discloses the tracheotomy tube of claim 4, wherein said collar is integral with the hollow tubular body (see fig.2)

As to **claim 7**, Fauza does not disclose the tracheotomy tube of claim 4, wherein said collar includes one or more barbs for attaching the collar to said hollow tubular body. However, applicant has not established criticalities regarding the attachment means including one or more barbs to be used in the invention. Therefore, Fauza's integral collar is considered to have some equivalent form of attachment means that is capable of securing collar to said hollow tubular body.

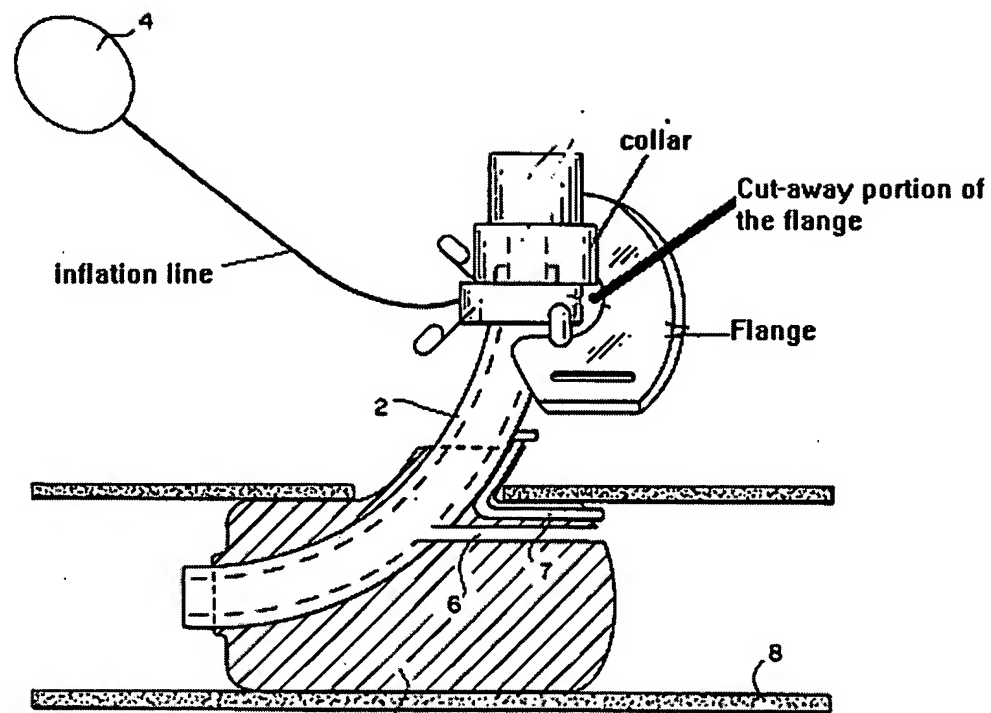


FIG. 2

PRIOR ART
U.S. Patent
US 6,612,305 B2

Allowable Subject Matter

Claims 12-31 are patentable over the prior art of record.

Claims 10, and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

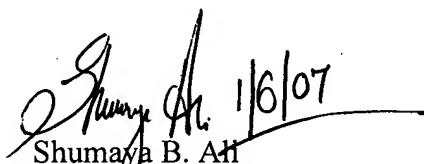
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ah
Examiner
Art Unit 3771


JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

1/21/07